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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,976	11/20/2003	Syed F.A. Hossainy	50623.317	2726
7590 07/19/2007				
Victor Repkin Squire, Sanders & Dempsey L.L.P. Suite 300 1 Maritime Plaza San Francisco, CA 94111				
			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 07/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,976	Applicant(s) HOSSAINY ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-21 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) 13-14 and 31-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 15-21, 23-30 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 06/26/2007 have been entered. The examiner notes that applicant's counsel has not provided the examiner with the support for the newly entered amendments. Generally it is considered good practice when entering new amendments to the claims to direct the examiners attention to where the support for the amendments can be found, such as within the specification or previous claim set. The terminal disclaimer filed 6/26/2007 has overcome the double patenting rejection over 10/925,257.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically there is no support within the specification for the limitation that the diblock copolymers coefficients m and n are **equal** to 2, there is only support within the original specification as filed that n and m are greater than 2. See [0018] of US PGPUB 20050112170 A1 of application 10/718976.

Response to Arguments

The rejection of claims 15 and 33 (claims 4 and 22 which are now limitations in claims 1 and 19) over 35 USC § 112 1st paragraph has been withdrawn. While applicants arguments were unclear regarding the support for hydrolysis of PLA (a reaction between DLPLA and PEG is a condensation reaction the opposite of hydrolysis) the examiner has withdrawn the rejection. Upon further consideration the examiner has concluded that hydrolysis of PLA was a well-known technique in the art, therefore applicants description of the process was sufficient for written description.

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 06/26/2007, with respect to the 35 U.S.C. 102(e) rejection over Schwarz et al. (US 2003/0203000 A1). has been fully considered and is persuasive because Schwarz does not recite the MW of the PLA polymers disclosed. The rejection over Schwarz has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5-12 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (US 6,258,121 B1), for the reasons set forth in the previous office action dated 03/26/2007.

Applicant's arguments filed 06/26/2007 have been fully considered but they are not persuasive.

Applicants asserts that Yang does not teach a medical coating of a derivative of carboxylated or hydrolyzed poly(lactic acid) having an average MW between about 1,000 and about 20,000.

The relevance of these assertions is unclear. As already described in the previous office action dated 03/26/2007 the limitation that PLA is a polymer that has undergone hydrolysis is not seen as having a patentable distinction over the PLA polymers of Yang. By further processing the copolymers by hydrolysis applicants are essentially shortening the PLA segments by degrading them, therefore the copolymers will essentially have a range of different sized PLA units. This is not seen as being patentably distinct from Yang's copolymers synthesized by coupling PEG to PLA, in which PLA is synthesized or purchased from a commercial source, the polymers will inherently have numerous lengths with varying molecular weights, therefore the additional treatment claimed by applicants does not give the claim any patentable distinction from the Yang reference. Both methods to make the copolymer would essentially result in PLA blocks of varying lengths, therefore the claimed invention is the same because the claims are to a medical article, not a method to hydrolyze a PLA polymer. Regarding applicants new limitation for the MW, Yang incorporates by reference the PLA-PEO copolymers of Kim et al (US 5,548,035) who teaches the use of PLA-PEO-PLA blocks. The length of the PLA polymers of Kim can be from 20-500, it is inherent that within this broad range applicants claimed MW range is met, for instance a

PLA polymer with 20 monomer units would have a MW ~1400-1500, 200 monomer units would be ~14,000-15,000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3,5-12,15-21,23-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,258,121 B1) in view of Okada et al. (US 6,113,943), for the reasons set forth in the previous office action dated 03/26/2007.

Applicant's arguments filed 06/26/2007 have been fully considered but they are not persuasive.

Applicants assert as above that Yang does not disclose a medical coating of a derivative of carboxylated or hydrolyzed poly(lactic acid) having an average MW between about 1,000 and about 20,000. Applicants also state that Okada does not describe carboxylated PLA or suggest PLA copolymers with a MW between 1,000 to 20,000 Daltons for medical devices. Lastly applicants state that there is no motivation to combine the two references above.

The arguments for Yang above are incorporated herein as well, therefore Yang meets the claimed MW. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Okada was used only for the disclosure within that it was advantageous to hydrolyze a polylactic acid for sustained release preparations. Therefor since the Okada is only used as a secondary reference it does not have to disclose all of applicants claimed invention. The motivation as already recited in the previous office action would be to provide a coated stent with a block copolymer comprising hydrolyzed lactic acid that would provide a sustained release preparation with a small initial burst of active ingredient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9,11,15,18,19-21,23-27,29 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,169,404 B1, for the reasons set forth in the previous office action dated 03/26/2007.

Applicants in their response filed 06/26/2007 state a terminal disclaimer has been filed for the above patent. However only a terminal disclaimer for application 10/925,257 has been filed, therefore the rejection still stands.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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SUPERVISORY PATENT EXAMINER